

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE      | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-----------------|------------------|----------------------|-------------------------|------------------|
| 10/810,116      | 03/26/2004       | Walter H. Olson      | P-2988.14               | 8025             |
| 27581 75        | 90 10/05/2005    |                      | EXAMINER                |                  |
| MEDTRONIC, INC. |                  |                      | EVANISKO, GEORGE ROBERT |                  |
| 710 MEDTRON     | NIC PARKWAY NE   |                      |                         |                  |
| MS-LC340        |                  |                      | ART UNIT                | PAPER NUMBER     |
| MINNEAPOLI      | S, MN 55432-5604 |                      | 3762                    |                  |

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | 1  | W |  |  |  |
|---|--|--|---|--|--|--|
|   | Application No.  | Applicant(s)   |   |  |  |  |
|   | 10/810,116   | OLSON ET AL.   |   |  |  |  |
| Office Action Summary   | Examiner   | Art Unit   |   |  |  |  |
|   | George R. Evanisko   | 3762   |   |  |  |  |
| The MAILING DATE of this communication a<br>Period for Reply  | ppears on the cover sheet wi   | th the correspondence address  |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perions are reply within the set or extended period for reply will, by state the provision of the provision of the maximum statutory perions are reply received by the Office later than three months after the main earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNIC<br>1.136(a). In no event, however, may a re<br>od will apply and will expire SIX (6) MON<br>tute, cause the application to become AB | CATION.  Peply be timely filed  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133). |   |  |  |  |
| Status  |  |  |   |  |  |  |
| 1) Responsive to communication(s) filed on 26   | March 2004.  |  |   |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) ⊠ Th  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.   |  |   |  |  |  |
| 3) Since this application is in condition for allow   |  | •  |   |  |  |  |
| closed in accordance with the practice under  | r <i>Ex par</i> te Quayle, 1935 C.D  | . 11, 453 O.G. 213.  |   |  |  |  |
| Disposition of Claims   |  |  |   |  |  |  |
| 4)⊠ Claim(s) <u>1-19</u> is/are pending in the application  | on.  |  |   |  |  |  |
| 4a) Of the above claim(s) is/are withdo   |  |  |   |  |  |  |
| 5) Claim(s) is/are allowed.   |  |  |   |  |  |  |
| 6)⊠ Claim(s) <u>1-19</u> is/are rejected.   |  |  |   |  |  |  |
| 7) Claim(s) is/are objected to.   |  |  |   |  |  |  |
| 8) Claim(s) are subject to restriction and  | I/or election requirement.   |  |   |  |  |  |
| Application Papers  |  |  |   |  |  |  |
| 9) The specification is objected to by the Exami  | ner.   |  |   |  |  |  |
| 10) The drawing(s) filed on is/are: a) a  |  | by the Examiner.   |   |  |  |  |
| Applicant may not request that any objection to the   | ne drawing(s) be held in abeyan  | ce. See 37 CFR 1.85(a).  |   |  |  |  |
| Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the  | •  |  |   |  |  |  |
| Priority under 35 U.S.C. § 119  |  |  |   |  |  |  |
| •   |  | 440(-) (-) (0  |   |  |  |  |
| 12) Acknowledgment is made of a claim for forei a) All b) Some * c) None of:  | gn priority under 35 U.S.C. §  | 119(a)-(d) or (t).   |   |  |  |  |
| 1. ☐ Certified copies of the priority docume  | ents have been received  |  |   |  |  |  |
| 2. Certified copies of the priority docume  |  | onlication No  |   |  |  |  |
| 3. Copies of the certified copies of the pr   |  |  |   |  |  |  |
| application from the International Bure   | •  | ū  |   |  |  |  |
| * See the attached detailed Office action for a li  |  | received.  |   |  |  |  |
| •   |  |  |   |  |  |  |
| •   |  |  |   |  |  |  |
| Attachment(s)   | ·  |  |   |  |  |  |
| 1) Notice of References Cited (PTO-892)   |  | ummary (PTO-413)   |   |  |  |  |
| <ol> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0</li> </ol>   |  | )/Mail Date formal Patent Application (PTO-152)  |   |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:  |  |   |  |  |  |

#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 10, and 15, "each clause" lacks antecedent basis (it is unclear if each rule has clauses and how many clauses are included in each rule). In the last paragraph, "cardiac rhythm management based" should be "cardiac rhythm management therapy based" since the therapy is being discussed.

In claim 9, the claim should depend from claim 7 since claim 7 discusses the cardioversion therapy.

In claim 10, the claim is vague since it can not be determined if the media, the instructions, or both are being positively recited and claimed. System claims can not solely claim instructions but must also include a tangible computer medium to hold the instructions.

#### Priority

This application discloses and claims subject matter disclosed in prior Application No. 08/413570, filed March 30, 1995, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Application/Control Number: 10/810,116 Page 3

Art Unit: 3762

It is unclear what prior applications this application is claiming priority to. The first page of the specification only states that priority is being claimed to 08/649145, but the declaration claims benefit to other prior applications, such as 08/413570, and not to 08/649145.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (f) he did not himself invent the subject matter sought to be patented.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra (5243980). Mehra teaches the sensing of atrial and ventricular events to define a cardiac grammar (columns 10 and 11), incorporates by reference several patents to define how detection of the different arrhythmias may function, and shows the priority-rule based logic set with a plurality of rules for delivery and withholding of therapy in figure 5e. In addition, Mehra teaches a plurality of anti-tachycardia pacing therapies and increasing defibrillation shocks after redetection/reconfirmation (columns 12-14) and teaches the use of nerve or drug stimulation (columns 2 and 17).

Claims 1-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Oslson et al (5545186)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1-15 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. This application includes another inventor, Mark Brown, which is not listed on the Olson et al patent, 5545186. Since claim 1 of the Olson patent covers claims 1, 10, and 15 of this application, the applicant did not invent the claimed subject matter.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mehra.

Mehra teaches the use of a microprocessor being controlled by RAM and DMA and a physician programming the device to deliver the particular therapies based on the particular arrhythmia (columns 11 and 12) and therefore provides a computer readable media with instructions to perform the method.

In the alternative, Mehra discloses the claimed invention except for the computer readable media containing instructions to perform the method. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ICD system and method with microprocessor and memory as taught by Mehra, with the computer readable media containing instructions to perform the method since it was known in the art that ICD systems and methods use a computer readable media containing instructions to perform the method to allow the system to function automatically and/or to allow the physician to be able to program the device to fit the particular patient.

Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra.

Mehra discloses the claimed invention except for the plurality of cardioversion therapies with different amounts (claim 7) and reconfirming the arrhythmia to deliver an increased cardioversion therapy (claim 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ICD method as taught by Mehra, with the plurality of cardioversion therapies with different amounts and reconfirming the arrhythmia to deliver an increased cardioversion therapy since it was known in the art that ICD methods use the plurality of cardioversion therapies with different amounts and reconfirming the arrhythmia

Art Unit: 3762

to deliver an increased cardioversion therapy to allow a higher level of cardioversion therapy to be delivered to the patient to quickly revert the arrhythmia if the first cardioversion therapy is not successful and the arrhythmia is still present.

## **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-17, 1-13, 1-10, 1-7, and 1 of U.S. Patent Nos. 6731978, 6487443, 6259947, 5991656, and 5545186, respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of the broader applications claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate into the patented claims the different therapies and reconfirmations prior to delivering a higher therapy and a computer readable media containing instructions to perform the method, since it was known in the art that ICD methods and systems use different therapies, such as ATP, cardioversion, drugs, and defibrillation to revert the arrhythmias, use a reconfirmation prior to delivery of a higher energy pulse, to make sure the arrhythmia is still occurring and to

Application/Control Number: 10/810,116 Page 7

Art Unit: 3762

increase the energy over the prior pulse which was not effective, and to use a computer readable media containing instructions to perform the method to allow the system to function automatically and/or to allow the physician to be able to program the device to fit the particular patient.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko Primary Examiner Art Unit 3762

GRE October 2, 2005